

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Appellant:	KIM et al.	Examiner:	Holmes, Rex R.
Serial No.:	10/735,519	Group Art Unit:	3762
Filed:	December 12, 2003	Docket No.:	GUID.160PA
Confirmation No.:	1580	Customer No.:	51294
Title:	CARDIAC RESPONSE CLASSIFICATION USING MULTISITE SENSING AND PACING		

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this paper is being electronically transmitted by EFS-WEB to the United States Patent and Trademark Office on January 11, 2010.

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**REPLY BRIEF**

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Sir:

This Reply Brief is submitted pursuant to 37 C.F.R. § 41.41 in response to the Examiner's Answer dated November 11, 2009. This submission is within two months of the Examiner's Answer and is thus believed to be timely filed.

This paper does not unnecessarily duplicate all of the various sections that were included in the Appeal Brief filed on or about August 7, 2009. We also do not repeat here all of the arguments set forth in the Arguments section of the original Appeal Brief. Instead, this paper includes only those sections specified in MPEP § 1208 as appropriate for a Reply Brief, and the Arguments section herein is intended to address the points raised in the Examiner's Answer.

No fee is believed to be due by the filing of this paper. If, however, this belief is incorrect, authority is given to charge/credit deposit account 50-3581 (GUID.160PA) any additional fees/overages in support of this filing.

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## **I. STATUS OF CLAIMS**

The original application as filed contained claims numbered 1 through 62, except that two different claims were inadvertently each numbered 44, and there was no claim numbered 49. Later in prosecution, the duplicative (second) claim number 44 was canceled (see Applicants' amendment of Sept. 11, 2006), claim 63 was added, and claims 24-34 and 61 were also later canceled. The claims were not renumbered in prosecution, and thus the claims of the present application are anomalous insofar as: (1) there continues to be no claim 49 even though no claim 49 was ever canceled, and (2) claim 44 is pending, even though a duplicative claim 44 was canceled.

Claims 1-23, 35-48, 50-60, 62, and 63 are thus currently pending in the application. Claims 24-34, duplicative claim 44, and claim 61 were previously canceled. Each of the pending claims has been finally rejected by the Examiner's action dated June 9, 2009 (hereinafter "Final Office Action"), from which Appellant appeals. All pending claims are therefore being appealed, and are listed in the Claims Appendix.

The Examiner's answer of November 11, 2009 states that the above statement, as included in the Appeal Brief of August 7, 2009, is correct in characterizing the status of the claims.

## **II. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

- A. Claims 1-23, 35-48, 50-60, 62, and 63 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

### III. ARGUMENT

#### A. **Rebuttal of Examiner's Arguments Regarding The Rejection Under 35 U.S.C. §112, first paragraph, of Claims 1-23, 35-48, 50-60, 62, and 63.**

##### 1. **Claims 1-23, 35-48, 50-60, 62, and 63.**

The Examiner's Answer appears to misapply §112, first paragraph in rejecting the claims. The "Grounds of Rejection" of the Examiner's Answer concludes that:

Applicants can only define over the prior art with limitations that they had possession of at the time of the invention. Since the negative limitation is not expressly set forth in the specification, it is considered new matter.

(Page 3).

A negative limitation that is not expressly recited in the Specification is not *ipso facto* considered new matter, as the above conclusion seems to imply. MPEP § 2173.05(i) provides that "a lack of literal basis in the specification for a negative limitation may not be sufficient to establish a *prima facie* case for lack of descriptive support." (Citing *Ex parte Parks*, 30 USPQ2d 1234, 1236 (Bd. Pat. App. & Inter. 1993)). Accordingly, the rejection is improper because it is based on the erroneous notion that "Since the negative limitation is not expressly set forth in the specification, it is considered new matter." (Page 3).

The claim elements at issue have proper support in satisfaction of §112, first paragraph. "An objective standard for determining compliance with the written description requirement is, 'does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed.'" (MPEP § 2163.02 quoting *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989)). For a negative limitation, proper §112, first paragraph analysis asks whether the negative limitation has basis in the original disclosure. (See MPEP § 2173.05(i) stating "Any negative limitation or exclusionary proviso must have basis in the original disclosure"). Indeed, the requisite basis for the claim elements at issue is found in the original disclosure.

For example, a person having ordinary skill in the art reviewing the disclosure is given sufficient information to appreciate recognition of distinguishing between captured,

non-captured, and fusion/pseudofusion responses using a single cardiac signal without using any other cardiac signal sensed following the pacing pulse. Figure 12 shows the sensing of one cardiac signal 1225, checking for noise 1226, and then discriminating non-capture 1235, fusion/pseudofusion 1245, and capture 1255, and based on the cardiac signal:

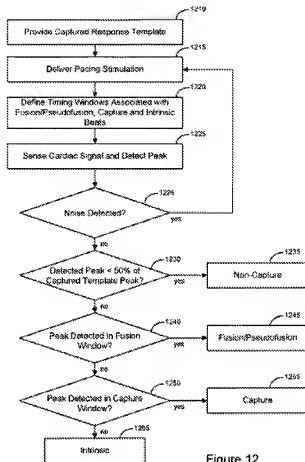


Figure 12

Figure 12 allows one having ordinary skill in the art to recognize discrimination being performed using the only signal mentioned without using any other signals (particularly considering the process is restarted if noise is detected 1226 after sensing 1225 the cardiac signal). Also note Page 35, Line 26-Page 36, Line 8 of the Specification discussing canceling pacing artifacts to yield “the portion of the cardiac signal representing the evoked response without the superimposed pacing artifact.” (Emphasis added).

As discussed above and further in the Appeal Brief, the original disclosure clearly includes the requisite basis for discrimination using a cardiac signal without using other signals, in the manner claimed.

The “Response to Argument” section of the Examiner’s Answer further states:

The specification is silent as to the system using or not using any other signal following the pacing pulse. The Appellant argues that the flow charts show that the system uses one signal. What is absent from the flow charts and the remaining parts of the written description is a description of using only a single signal **without** using any other signals. (Pages 4-5; emphasis original).

Appellant respectfully disagrees. It is unclear how one having ordinary skill in the art would view Figure 12 (reproduced above) and think that the Application lacks disclosure of “using only a single signal **without** using any other signals.” (Id.; emphasis original). Figure 12 only mentions one signal in capture discrimination, as shown above. The Examiner’s Answer does not explain why one having ordinary skill in the art would necessarily think that other unmentioned signals must be used in the discrimination, and that the discrimination could not be based solely on the one signal (the cardiac signal sensed in 1225) shown in the flow chart. It would be perfectly reasonable for one having ordinary skill in the art to conclude that the discrimination of Figure 12 could be performed using the sole signal referenced in the flow chart without some other unmentioned signals.

The “Response to Argument” section of the Examiner’s Answer further posits several hypothetical scenarios (regarding beat to beat comparison and pressure pulses) and warns of “free reign to claim anything by exclusion.” (Pages 4-5). Without acquiescence to the hypothetical scenarios, which are not presently at issue, Appellant notes that in each case it would be appropriate to ask whether each limitation had basis in the original disclosure to properly contain claim scope. (MPEP § 2173.05(i)). For the particular element at issue on Appeal, a person having ordinary skill in the art reviewing the disclosure would find basis for distinguishing between captured, non-captured, and fusion/pseudofusion responses using a single cardiac signal without using any other cardiac signal sensed following the pacing pulse, as discussed above and in the Appeal Brief.

For each of the reasons discussed above, Appellant respectfully submits that the limitations of claims 1-23, 35-48, 50-60, 62, and 63 do have basis in the original disclosure in satisfaction of §112, first paragraph, and that the rejection of these claims should be reversed.

#### **IV. CONCLUSION**

In view of the foregoing arguments, as well as the arguments presented in the Appeal Brief, Appellant respectfully submits that the claimed invention is patentable over the cited reference and that the rejections of claims 1-23, 35-48, 50-60, 62, and 63 should be reversed. Appellant respectfully requests reversal of the rejections as applied to the appealed claims and allowance of the entire application.

Respectfully submitted,

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